

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No. 8217
EITAN KONSTANTINO et al.	Examiner: NGUYEN, VI X
Application No.: 10/810,330	Technology Center/Art Unit: 3734
Filed: June 25, 2004	
For: APPARATUS AND METHODS FOR TREATING HARDENED VASCULAR LESIONS	<u>DECLARATION OF MICHAEL EVANS</u>
Customer No.: 20350	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Michael A. Evans, declare as follows.

1. I am a named inventor on U.S. Patent Publication 2002/0010487 (the “‘487 publication”).

2. The device described in the ‘487 publication is a shearing device having counter-rotating helical blades 20 and 30. Optionally, a driveshaft 32 having a helical pumping member 42 disposed thereover may be provided within the shearing blades in order to assist in removal of thrombus or other material cut by the shearing blades.

3. The ‘487 publication never teaches or suggests that a balloon or any other expandable, inflatable component would be coupled to shearing blades 20 and 30 to expand said shearing blades or for any other purpose.

4. The balloons referred to in paragraphs 68 and 80 of the ‘487 publication are distal isolation or protection balloons which would be deployed at a location distal to the

4. The balloons referred to in paragraphs 68 and 80 of the '487 publication are distal isolation or protection balloons which would be deployed at a location distal to the distal tip of the shearing catheter, not within the shearing blades. Alternatively, as described in paragraph 68, a balloon could be provided as part of a sheath disposed around the catheter body proximal to the shearing blades. The purpose of these balloons is to contain the region around the blades to prevent emboli release. Inflating these balloons or any other equivalent components within the internal volume defined by the shearing blades would both (1) fail to provide for emboli protection and (2) interfere with the purpose of the shearing blades, which is to shear thrombotic material and capture material within the interior defined by said shearing blades.

5. I further declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 1/24/2009


Michael A. Evans